IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC.,	:	
Plaintiff/Counterclaim-Defendant,	:	
v.	:	Civil Action No. 13-1729 (SLR)
AMNEAL PHARMACEUTICALS LLC,	:	
Defendant/Counterclaimant.	:	

DEFENDANT AMNEAL PHARMACEUTICALS LLC'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS
TO PLAINTIFF'S AMENDED COMPLAINT

Defendant Amneal Pharmaceuticals LLC ("Amneal"), by and through undersigned counsel, answers the Amended Complaint for Patent Infringement ("Complaint") of Plaintiff Takeda Pharmaceuticals U.S.A. ("Takeda") as follows:

I. ANSWER

NATURE OF THE ACTION

1. Amneal admits that Takeda has filed an action for purported patent infringement of U.S. Patent No, 7,906,519 ("the '519 patent"); U.S. Patent No. 7,935,731 ("the '731 patent"); U.S. Patent No. 8,093,298 ("the '298 patent"); U.S. Patent No. 7,964,648 ("the '648 patent); U.S. Patent No. 8,093,297 ("the '297 patent"); U.S. Pat. Nos. 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent"). Amneal further admits that it

has filed Abbreviated New Drug Application ("ANDA") No. 20-4711 with the United States Food and Drug Administration ("FDA"). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 1 of the Complaint.

THE PARTIES

2. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint, and therefore denies them.

3. Amneal admits that Amneal Pharmaceuticals LLC is a corporation organized under the laws of the State of Delaware, previously having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey 08807. At present, Amneal Pharmaceuticals LLC has a principle place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863. Amneal admits that it is in the business of manufacturing, marketing and selling high quality pharmaceutical products in the United States, including the State of Delaware. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. Paragraph 4 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal does not contest that this is an action for patent infringement arising under 35 U.S.C. § 271.

5. Paragraph 5 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal does not contest that this Court has jurisdiction over the subject matter of the Complaint.

6. Paragraph 6 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it is not

contesting the personal jurisdiction of this Court over Amneal Pharmaceuticals LLC, solely for the purposes of this litigation. Amneal admits that it is a Delaware Corporation and that it has previously submitted to the personal jurisdiction of this Court on limited bases, and that it has previously asserted counterclaims in other actions within the District. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 6 of the Complaint.

7. Paragraph 7 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal does not contest that venue is proper.

STATEMENT OF FACTS RELEVANT TO ALL COUNTS

8. On information and belief, Amneal admits that according to publicly available FDA information, COLCRYS® is indicated for the "prophylaxis and treatment of gout flares in adults." Except as expressly admitted, Amneal denies the remaining allegations in paragraph 8 of the Complaint.

9. On information and belief, Amneal admits that according to publicly available FDA information, COLCRYS® is indicated for "Familial Mediterranean Fever (FMF) in adults and children 4 years or older." Except as expressly admitted, Amneal denies the remaining allegations of paragraph 9 of the Complaint.

10. On information and belief, Amneal admits that according to publicly available FDA information, NDA Nos. 22-351, 22-352 and 22-353 have been approved by the FDA. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 10 of the Complaint.

11. On information and belief, Amneal admits that the FDA's website shows an orphan drug exclusivity expiration date of July 29, 2016 for COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 11 of the Complaint.

12. On information and belief, Amneal admits that according to publicly available FDA information, COLCRYS® was approved for marketing in the United States in 2009. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 12 of the Complaint.

13. Paragraph 13 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 13 of the Complaint, and therefore denies the allegations.

A. Amneal admits that the '519 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Ingredient," with a stated issue date of March 15, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13A of the Complaint.

B. Amneal admits that the '731 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of May 3, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13B of the Complaint.

C. Amneal admits that the '298 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated

issue date of January 10, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13C of the Complaint.

D. Amneal admits that the '648 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13D of the Complaint.

E. Amneal admits that the '297 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13E of the Complaint.

F. Amneal admits that the '004 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of November 17, 2009, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13F of the Complaint.

G. Amneal admits that the '758 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares," with a stated issue date of October 13, 2009, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13G of the Complaint.

H. Amneal admits that the '681 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of October 26, 2010, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13H of the Complaint.

I. Amneal admits that the '269 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of March 29, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13I of the Complaint.

J. Amneal admits that the '647 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13J of the Complaint.

K. Amneal admits that the '938 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of July 19, 2011, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13K of the Complaint.

L. Amneal admits that the '296 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13L of the Complaint.

M. Amneal admits that the '655 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 17, 2012, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13M of the Complaint.

N. Amneal admits that the '395 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as inventors. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13N of the Complaint.

O. Amneal admits that the '396 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as inventors. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13O of the Complaint.

P. Amneal admits that the '721 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of May 14, 2013, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13P of the complaint.

Q. Amneal admits that the '722 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Ingredient," with a stated issue date of May 14, 2013, naming on its face Matthew Davis as the inventor. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 13Q of the Complaint.

14. Amneal admits that the '519, '731, '298, '648, and '297 patents are collectively referred to in the Complaint as the "FMF Patents."

15. Amneal admits that the '004, '758, '681, '269, '647, '648, '938, '296, '297, '655, '395, '396, '721 and '722 patents are collectively referred to in the Complaint as the "Gout Patents."

16. Amneal admits that all of the above-listed patents are collectively referred to in the Complaint as the "COLCRYS® Patents."

17. On information and belief, Amneal admits that according to publicly available FDA information, certain patent information purportedly relating to NDA Nos. 22-351, 22-352 and 22-353 is included in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as "the Orange Book"). Except as expressly admitted, Amneal denies the remaining allegations in paragraph 17 of the Complaint.

THE GOUT AND FMF MARKETS IN THE UNITED STATES

18. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint, and therefore denies them.

19. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 of the Complaint, and therefore denies them.

20. Denied.

PHYSICIAN AND PHARMACY PRESCRIBING PRACTICES

21. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 21 of the Complaint, and therefore denies them.

22. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint, and therefore denies them.

23. Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23 of the Complaint, and therefore denies them.

AMNEAL'S ACTIONS GIVING RISE TO THIS SUIT

24. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® prior to the purported expiration of the Patents asserted in the Complaint. Amneal denies that such asserted patents are valid and/or enforceable, and/or properly listed in the Orange Book, and therefore, except as expressly admitted, Amneal denies the remaining allegations in paragraph 24 of the Complaint.

25. Paragraph 25 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it provided Takeda with an executed letter ("Amneal's First Paragraph IV Notice Letter") dated February 20, 2013, providing notice that Amneal had filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS®, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '648 and '297 patents, for the treatment and prevention of gout flares and not for the treatment of FMF. Further, to the extent that a response is required, Amneal admits that Amneal's First Paragraph IV Notice Letter asserts, *inter alia*, that the '648 and '297 patents are invalid and/or not infringed by Amneal's 0.6 mg oral tablet generic version of COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 25 of the Complaint.

26. Paragraph 26 is proffered as a legal conclusion to which Amneal believes no response is required. Further, Amneal is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 26. To the extent that a response is required and the averment is understood, Amneal admits that Takeda brought suit against Amneal within

45 days of receipt of Amneal's First Paragraph IV Letter, alleging, *inter alia*, patent infringement of the '648 and '297 patents, related to Amneal's 0.6 mg oral tablet generic version of COLCRYS® for the treatment and prevention of gout flares. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 26 of the Complaint.

27. Amneal admits that it notified Takeda on August 28, 2013 that it would be seeking FDA approval of its ANDA No. 20-4711 for the treatment of FMF, and not for the treatment and prevention of gout flares. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 27 of the Complaint.

28. Paragraph 28 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it provided Takeda with an executed letter ("Amneal's Second Paragraph IV Notice Letter") dated September 9, 2013, providing notice that Amneal had amended ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS®, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), with respect to the FMF Patents, for the treatment of FMF. Further to the extent that a response is required, Amneal admits that Amneal's Second Paragraph IV Notice Letter asserts that all of the asserted FMF patents in the Complaint are invalid and/or not infringed by Amneal's 0.6 mg oral tablet generic version of COLCRYS®. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 28 of the Complaint.

29. Amneal admits that it is seeking FDA approval of its ANDA No. 20-4711 for the treatment of FMF, and not for the treatment and prevention of gout flares. Amneal further admits that in Amneal's Second Paragraph IV Notice Letter, Section IV, it stated that "Amneal's ANDA product will be marketed solely for the approved indication of treatment of familial

Mediterranean fever ("FMF") in adults and children 4 years or older." Except as expressly admitted, Amneal denies the remaining allegations in paragraph 29 of the Complaint.

30. Paragraph 30 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal admits that it submitted a labeling amendment to the FDA on September 6, 2013 concerning ANDA No. 20-4711, indicating that it was seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 30 of the Complaint.

31. Paragraph 31 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal denies the allegations in paragraph 31 of the Complaint.

32. Paragraph 32 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal denies the allegations in paragraph 32 of the Complaint.

33. Paragraph 33 is proffered as a legal conclusion to which Amneal believes no response is required. To the extent that a response is required, Amneal denies the allegations in paragraph 33 of the Complaint.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Amneal admits that is has filed ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS®, including a certification under 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), with respect to the FMF Patents, for the treatment of FMF. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 38 of the Complaint.

39. Amneal admits that it has knowledge of the Gout Patents. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 39 of the Complaint.

40. Denied.

41. Admitted.

COUNT I

(Purported) Infringement of the '519 Patent

42. Amneal repeats its answers to paragraphs 1-41 as if fully set forth herein.

43. Denied.

44. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF prior to the purported expiration of the '519 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 44 of the Complaint.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

COUNT II

(Purported) Infringement of the '731 Patent

49. Amneal repeats its answers to paragraphs 1-48 as if fully set forth herein.

50. Denied.

51. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF prior to the purported expiration of the '731 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 51 of the Complaint.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

COUNT III

(Purported) Infringement of the '298 Patent

56. Amneal repeats its answers to paragraphs 1-55 as if fully set forth herein.

57. Denied.

58. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF prior to the purported expiration of the '298 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 58 of the Complaint.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

COUNT IV

(Purported) Infringement of the '648 Patent

63. Amneal repeats its answers to paragraphs 1-62 as if fully set forth herein.

64. Denied.

65. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF prior to the purported expiration of the '648 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 65 of the Complaint.

66. Denied.

67. Amneal admits that it has knowledge of the '648 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 67 of the Complaint.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

COUNT V

(Purported) Infringement of the '297 Patent

72. Amneal repeats its answers to paragraphs 1-71 as if fully set forth herein.

73. Denied.

74. Amneal admits that it has submitted ANDA No. 20-4711 to the FDA with a Paragraph IV Certification, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF prior to the purported expiration of the '297 patent.

Except as expressly admitted, Amneal denies the remaining allegations in paragraph 74 of the Complaint.

75. Denied.

76. Amneal admits that it has knowledge of the ‘297 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 76 of the Complaint.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

COUNT VI

(Purported) Infringement of the ‘004 Patent

81. Amneal repeats its answers to paragraphs 1-80 as if fully set forth herein.

82. Amneal admits that it has knowledge of the ‘004 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 82 of the Complaint.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT VII

(Purported) Infringement of the ‘758 Patent

87. Amneal repeats its answers to paragraphs 1-86 as if fully set forth herein.

88. Amneal admits that it has knowledge of the ‘758 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 88 of the Complaint.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

COUNT VIII

(Purported) Infringement of the '681 Patent

93. Amneal repeats its answers to paragraphs 1-92 as if fully set forth herein.

94. Amneal admits that it has knowledge of the '681 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 94 of the Complaint.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

COUNT IX

(Purported) Infringement of the '269 Patent

99. Amneal repeats its answers to paragraphs 1-98 as if fully set forth herein.

100. Amneal admits that it has knowledge of the '269 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 100 of the Complaint.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

COUNT X

(Purported) Infringement of the '647 Patent

105. Amneal repeats its answers to paragraphs 1-104 as if fully set forth herein.

106. Amneal admits that it has knowledge of the '647 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 106 of the Complaint.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

COUNT XI

(Purported) Infringement of the '938 Patent

111. Amneal repeats its answers to paragraphs 1-110 as if fully set forth herein.

112. Amneal admits that it has knowledge of the '938 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 112 of the Complaint.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

COUNT XII

(Purported) Infringement of the '296 Patent

117. Amneal repeats its answers to paragraphs 1-116 as if fully set forth herein.

118. Amneal admits that it has knowledge of the '296 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 118 of the Complaint.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

COUNT XIII

(Purported) Infringement of the '655 Patent

123. Amneal repeats its answers to paragraphs 1-122 as if fully set forth herein.

124. Amneal admits that it has knowledge of the '655 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 124 of the Complaint.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

COUNT XIV

(Purported) Infringement of the '395 Patent

129. Amneal repeats its answers to paragraphs 1-128 as if fully set forth herein.

130. Amneal admits that it has knowledge of the '395 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 130 of the Complaint.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

COUNT XV

(Purported) Infringement of the '396 Patent

135. Amneal repeats its answers to paragraphs 1-134 as if fully set forth herein.

136. Amneal admits that it has knowledge of the '396 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 136 of the Complaint.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

COUNT XVI

(Purported) Infringement of the '721 Patent

141. Amneal repeats its answers to paragraphs 1-140 as if fully set forth herein.

142. Amneal admits that it has knowledge of the '721 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 142 of the Complaint.

143. Denied.

144. Denied.

145. Denied.

146. Denied.

COUNT XVII

(Purported) Infringement of the '722 Patent

147. Amneal repeats its answers to paragraphs 1-146 as if fully set forth herein.

148. Amneal admits that it has knowledge of the '722 patent. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 148 of the Complaint.

149. Denied.

150. Denied.

151. Denied.

152. Denied.

EXCEPTIONAL CASE

153. Amneal admits that prior to the submission of a labeling amendment to the FDA on September 6, 2013, related to ANDA No. 20-4711, Amneal was aware of the existence of the COLCRYS® Patents. Except as expressly admitted, Amneal denies the remaining allegations in paragraph 153 of the Complaint.

154. Denied.

PRAYER FOR RELIEF

Amneal denies that Plaintiffs are entitled to the judgment and relief set forth in paragraphs (A) through (H) on pages 31-32 of the Complaint, or any relief for the allegations set forth in the Complaint.

II. AFFIRMATIVE DEFENSES

In further answer to the Complaint and as separate, affirmative defenses thereto, Amneal alleges as follows. Amneal expressly reserves the right to assert additional defenses that would be rendered appropriate in view of future discovery, information, and/or analysis.

First Affirmative Defense: Noninfringement

155. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '519 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

156. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '731 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

157. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '298 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

158. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '648 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

159. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '297 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

160. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '004 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

161. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '758 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

162. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '681 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

163. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '269 patent directly, indirectly, by inducement, contributorily,

literally or under the doctrine of equivalents, or in any other manner.

164. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '647 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

165. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '938 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

166. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '296 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

167. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '655 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

168. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '395 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

169. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '396 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

170. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '721 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

171. Amneal has not infringed, does not currently infringe, and will not infringe any

valid and enforceable claim of the '722 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

Second Affirmative Defense: Invalidity

172. Each and every claim of the '519 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

173. Each and every claim of the '731 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

174. Each and every claim of the '298 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

175. Each and every claim of the '648 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

176. Each and every claim of the '297 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

177. Each and every claim of the '004 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

178. Each and every claim of the ‘758 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

179. Each and every claim of the ‘681 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

180. Each and every claim of the ‘269 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

181. Each and every claim of the ‘647 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

182. Each and every claim of the ‘938 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

183. Each and every claim of the ‘296 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

184. Each and every claim of the ‘655 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

185. Each and every claim of the '395 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

186. Each and every claim of the '396 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

187. Each and every claim of the '721 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

188. Each and every claim of the '722 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Affirmative Defense: Prosecution History Estoppel

189. On information and belief Takeda is estopped from asserting any scope of the '519 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the '519 patent.

190. On information and belief Takeda is estopped from asserting any scope of the '731 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the '731 patent.

191. On information and belief Takeda is estopped from asserting any scope of the '298 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS®

because of statements made during the prosecution of the application leading to the issuance of the ‘298 patent.

192. On information and belief Takeda is estopped from asserting any scope of the ‘648 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘648 patent.

193. On information and belief Takeda is estopped from asserting any scope of the ‘297 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘297 patent.

194. On information and belief Takeda is estopped from asserting any scope of the ‘004 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘004 patent.

195. On information and belief Takeda is estopped from asserting any scope of the ‘758 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘758 patent.

196. On information and belief Takeda is estopped from asserting any scope of the ‘681 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘681 patent.

197. On information and belief Takeda is estopped from asserting any scope of the

‘269 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘269 patent.

198. On information and belief Takeda is estopped from asserting any scope of the ‘647 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘647 patent.

199. On information and belief Takeda is estopped from asserting any scope of the ‘938 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘938 patent.

200. On information and belief Takeda is estopped from asserting any scope of the ‘296 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘296 patent.

201. On information and belief Takeda is estopped from asserting any scope of the ‘655 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘655 patent.

202. On information and belief Takeda is estopped from asserting any scope of the ‘395 patent that would cover Amneal’s 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the ‘395 patent.

203. On information and belief Takeda is estopped from asserting any scope of the '396 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the '396 patent.

204. On information and belief Takeda is estopped from asserting any scope of the '721 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the '721 patent.

205. On information and belief Takeda is estopped from asserting any scope of the '722 patent that would cover Amneal's 0.6 mg oral tablet generic version of COLCRYS® because of statements made during the prosecution of the application leading to the issuance of the '722 patent.

III. COUNTERCLAIMS

206. For its counterclaims against Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"), Counterclaimant Amneal Pharmaceuticals LLC ("Amneal") asserts that Amneal's 0.6 mg colchicine product, as described and indicated in amended ANDA No. 20-4711, does not directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, infringe U.S. Pat. Nos. 7,906,519 ("the '519 patent"); 7,395,731 ("the '731 patent"); 8,093,298 ("the '298 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively "the

patents-in-suit"), and/or such patents are invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112. Amneal further asserts that certain of the patents-in-suit are improperly listed in the Orange Book.

PARTIES

207. Counterclaimant Amneal Pharmaceuticals LLC is a corporation organized under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey, 08807-2863. Amneal is in the business of manufacturing, marketing and selling high quality pharmaceutical products in the United States, including the State of Delaware.

208. On information and belief, and as stated by the Plaintiff in its Complaint, Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

NATURE OF THE ACTION

209. The counterclaims herein arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under 21 U.S.C. § 355. Amneal seeks entry of a declaratory judgment order that the patents-in-suit are not infringed by Amneal's 0.6 mg colchicine product for the indication described in its amended ANDA, and/or an order that the patents-in-suit are invalid and unenforceable. Further, Amneal seeks entry of an order requiring Takeda to delete the '519, '731, '298, '648, '297, '004, '758, '681, '269, '296, '655, '721, and '722 patents from the listing of patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as "the Orange Book") for COLCRYS®.

JURISDICTION AND VENUE

210. This Court has jurisdiction over the asserted counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a), the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(c)(3)(D) and 21 U.S.C. § 355(j)(5)(c)(ii)(I).

211. Takeda has submitted to personal jurisdiction in this Court by bringing suit against Amneal in this Court. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and as a result of Takeda's choice of forum.

212. The counterclaims encompass an action based on an actual controversy between Amneal and Takeda concerning the non-infringement and/or invalidity of the patents-in-suit, and/or improper Orange Book listing of certain of the patents-in-suit.

BACKGROUND

213. The patents-in-suit, which are the subject of Amneal's counterclaims, are as follows:

A. The '519 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of March 15, 2011, naming on its face Matthew Davis as the inventor.

B. The '731 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of May 11, 2011, naming on its face Matthew Davis as the inventor.

C. The '298 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

D. The ‘648 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

E. The ‘297 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

F. The ‘519, ‘731, ‘298, ‘648, and ‘297 patents are collectively referred to herein as the “FMF Patents.”

G. The ‘004 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of November 17, 2009, naming on its face Matthew Davis as the inventor.

H. The ‘758 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares,” with a stated issue date of October 13, 2009, naming on its face Matthew Davis as the inventor.

I. The ‘681 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of October 26, 2010, naming on its face Matthew Davis as the inventor.

J. The ‘269 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of March 29, 2011, naming on its face Matthew Davis as the inventor.

K. The ‘647 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

L. The ‘938 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of July 19, 2011, naming on its face Matthew Davis as the inventor.

M. The ‘296 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

N. The ‘655 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 17, 2012, naming on its face Matthew Davis as the inventor.

O. The ‘395 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

P. The ‘396 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

Q. The ‘721 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

R. The ‘722 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

214. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns the patents-in-suit.

215. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns NDA Nos. 22-351, 22-352 and 22-353 related to colchicine, sold in the U.S. under the name COLCRYS®.

216. On information and belief, the FDA approved Takeda's NDA No. 22-351 on July 30, 2009, NDA No. 22-352 on July 29, 2009, and NDA No. 22-353 on October 16, 2009.

217. On information and belief, certain patent information purportedly relating to NDA Nos. 22-351, 22-352 and 22-353 is included in the Orange Book; all of the patents-in-suit have been Orange Book listed by Takeda.

218. Amneal filed a labeling amendment to its Abbreviated New Drug Application ("ANDA") No. 20-4711 with the United States Food and Drug Administration ("FDA") on September 6, 2013, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF, prior to the purported expiration of the patents-in-suit. Amneal provided Takeda with an executed letter ("Amneal's Second Paragraph IV Notice Letter") dated September 9, 2013, providing notice that Amneal had amended ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), with respect to the FMF patents. In Amneal's Second Paragraph IV Notice Letter, Amneal averred that the FMF patents are invalid and/or are not infringed by Amneal's 0.6 mg oral tablet generic version of COLCRYS® for FMF.

219. Takeda filed a patent infringement Complaint against Amneal in this Court on October 21, 2013, alleging infringement of the FMF patents, and on September 4, 2014, Takeda filed an Amended Complaint alleging infringement of the patents-in-suit.

220. Amneal has denied and denies that it has infringed, currently infringes or will infringe, directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. Amneal has further asserted and asserts that the claims of the patents-in-suit are invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

221. Based on Takeda's filing of the Complaint, and Amneal's denial of Takeda's claims and Amneal's assertion of affirmative defenses, an actual controversy exists between the parties as to whether Amneal has infringed, is currently infringing or will infringe any valid and enforceable claim of the patents-in-suit, whether any of the patents-in-suit are valid, and whether certain of the patents-in-suit have been improperly listed in the Orange Book.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-Infringement of the Patents-in-Suit

222. Amneal repeats and realleges paragraphs 206-221 as if fully set forth herein.

223. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '519 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

224. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '731 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

225. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '298 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

226. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘648 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

227. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘297 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

228. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘004 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

229. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘758 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

230. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘681 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

231. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘269 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

232. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘647 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

233. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘938 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

234. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘296 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

235. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘655 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

236. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘395 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

237. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘396 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

238. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘721 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

239. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ‘722 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity of the Patents-in-Suit

240. Amneal repeats and realleges paragraphs 206-239 as if fully set forth herein.

241. Each and every claim of the '519 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

242. Each and every claim of the '731 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

243. Each and every claim of the '298 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

244. Each and every claim of the '648 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

245. Each and every claim of the '297 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

246. Each and every claim of the '004 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

247. Each and every claim of the ‘758 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

248. Each and every claim of the ‘681 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

249. Each and every claim of the ‘269 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

250. Each and every claim of the ‘647 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

251. Each and every claim of the ‘938 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

252. Each and every claim of the ‘296 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

253. Each and every claim of the ‘655 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

254. Each and every claim of the ‘395 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

255. Each and every claim of the ‘396 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

256. Each and every claim of the ‘721 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

257. Each and every claim of the ‘722 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD COUNTERCLAIM

Delisting of the ‘519, 731, ‘298, ‘648, ‘297, ‘004, ‘758, ‘681, ‘269, ‘296, ‘655, ‘721 and ‘722 Patents

258. Amneal repeats and realleges paragraphs 206-257 as if fully set forth herein.

259. 21 U.S.C. § 355(j)(5)(c)(ii)(I) provides an ANDA holder with a counterclaim cause of action to seek an order requiring an NDA holder to delete patent information in an Orange Book listing on the ground that the patent does not claim either the drug for which the NDA was approved or an approved method of using the drug.

260. COLCRYS® has been approved by the FDA as a single-ingredient oral colchicine product for the following indications:

- Prophylaxis and Treatment of Gout Flares in adults and

- Familial Mediterranean fever (FMF) in adults and children 4 years or older.

261. COLCRYS® has been approved by the FDA with the following dosage and administration regimen:

- Gout Flares:
  Prophylaxis of Gout Flares: 0.6 mg once or twice daily in adults and adolescents older than 16 years of age. Maximum dose 1.2 mg/day.
  Treatment of Gout Flares: 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) one hour later.

- FMF: Adults and Children older than 12 years 1.2 – 2.4 mg; Children 6 to 12 years 0.9 – 1.8 mg; Children 4 to 6 years 0.3 – 1.8 mg.
  - Give total daily dose in one or two divided doses.
  - Increase or decrease the dose as indicated and as tolerated in increments of 0.3 mg/day, not to exceed the maximum recommended daily dose.

262. The FDA approved usage codes for COLCRYS® are as follows:

U-1007: Method of Treating Gout Flares;

U-1020: Method for Using Colchicine for the Prophylaxis of Gout Flares;

U-1116: Method of Administering Colchicine to Familial Mediterranean Fever Patients;

U-1161: For the Treatment and Prophylaxis of Gout Flares & the Treatment of Familial Mediterranean Fever; and

U-1166: A Method for Treatment of Gout Flares during Prophylaxis.

263. Takeda has listed the ‘519, 731, ‘298, ‘648, ‘297, ‘004, ‘758, ‘681, ‘269, ‘296, ‘655, ‘721 and ‘722 patents in the Orange Book in relation to NDA Nos. 22-351, 22-352 and 22-353 and its colchicine product, sold in the U.S. under the name COLCRYS®.

264. The claims of each of the ‘519, 731, ‘298, ‘648, ‘297, ‘004, ‘758, ‘681, ‘269, ‘296, ‘655, ‘721 and ‘722 patents recite methods for the concomitant administration of colchicine and a drug other than colchicine.

265. No claim of the ‘519, 731, ‘298, ‘648, ‘297, ‘004, ‘758, ‘681, ‘269, ‘296, ‘655, ‘721 and ‘722 patents covers the drug colchicine or an approved method of using COLCRYS®, based on the FDA approved indications, the approved dosage and administration statements and the usage codes stated for COLCRYS®.

266. The listing of the ‘519 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

267. The listing of the ‘731 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

268. The listing of the ‘298 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

269. The listing of the ‘648 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

270. The listing of the ‘297 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

271. The listing of the ‘004 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

272. The listing of the ‘758 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

273. The listing of the ‘681 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

274. The listing of the '269 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

275. The listing of the '296 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

276. The listing of the '655 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

277. The listing of the '721 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

278. The listing of the '722 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

DEMAND FOR JUDGMENT

WHEREFORE, Amneal prays for the following relief:

A. Dismissal of all claims against Amneal with prejudice and denying all relief requested by Plaintiffs;

B. A declaration that Amneal has not infringed and will not infringe, directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner, any valid and enforceable claim of the patents-in-suit;

C. A declaration that Amneal has a lawful right to obtain FDA approval of its ANDA No. 20-4711 for its 0.6 mg colchicine product for FMF;

D. A declaration that Amneal has a lawful right to manufacture, use, import, market, sell and/or offer to sell its 0.6 mg colchicine ANDA product for the treatment of FMF upon approval by the FDA;

E. A declaration that all claims of all of the patents-in-suit are invalid;

F. A declaration that the '519, 731, '298, '648, '297, '004, '758, '681, '269, '296, '655, '721 and '722 patents are improperly listed in the Orange Book for COLCRYS®, including an order requiring that Plaintiff delist such patents with the FDA;

G. An injunction enjoining the Plaintiff, their officers, employees, agents, representatives, attorneys and others acting on their behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers or suppliers, doctors, patients, or any prospective or present sellers, dealers, distributors or customers of Amneal, or charging them either orally or in writing with infringement of any of the patents-in-suit;

H. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Amneal is entitled to recover its reasonable attorney's fees and costs upon prevailing in this action; and

I. An award to Amneal of such further relief as this Court may deem necessary, just and proper.

Dated: September 19, 2014

/s/ Mary B. Matterer

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